Amendment

Please amend the application as follows:

In the Specification

Delete -- Table IX. -- on page 66, line 11, and insert -- Table XIII. --.

Immediately following the last page of the claims, add a new page, containing the following abstract:

Abstract

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This invention relates to FSH or a FSH variant containing an alpha and beta subunit in formulations, and articles of manufacture. In one aspect the invention provides advantageous new multiuse pharmaceutical solutions, formulations, and products where none approved for commercial use had previously existed with extended use. These products are particularly useful in therapeutic regimens for increasing serum levels of FSH or an FSH variant over a period of treatment. Thus, *inter alia,* the invention fills the need for convenient products of FSH or from an FSH variant.

In the Claims

Delete Claims 92-106 and 110-117.

Please add new Claims 141-158:

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141. (New) A stable, pharmaceutically acceptable, solution formulation suitable for multi-use comprising FSH or an FSH variant, containing an alpha and a beta subunit and a preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben, benzalkonium chloride, benzethonium chloride, sodium dehydroacetate, thimerosal, and mixtures thereof, in an aqueous diluent; wherein, when stored for 3 months at room temperature or below, the solution formulation retains the same level of heterodimer content as that of a control formulation that is identical to the solution formulation except for lacking preservative, and that is stored under the identical conditions.

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142. (New) A stable, pharmaceutically acceptable, solution formulation suitable for multi-use comprising FSH or an FSH variant, containing an alpha and a beta subunit and a preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben, benzalkonium chloride, benzethonium chloride, sodium dehydroacetate, thimerosal, and mixtures thereof, in an aqueous diluent; wherein, when stored for 237 days at room temperature or below, the solution formulation retains the same level of heterodimer content as that of a control formulation that is identical to the solution formulation except for lacking preservative, and that is stored under the identical conditions.

143. (New) The solution formulation of either Claim 141 or Claim 142, wherein the FSH is human FSH.

144. (New) The solution formulation of either Claim 141 or Claim 142, wherein the FSH is an FSH variant, wherein the α-subunit has an amino acid sequence given in SEQ ID NO:5:

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS;

and wherein the ß-subunit has an amino acid sequence given in SEQ ID NO:11:

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELV
YETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGE.

145. (New) The solution formulation of either Claim 141 or Claim 142, wherein the preservative is benzyl alcohol.

146. (New) The solution formulation of Claim 145, wherein the FSH is human FSH.

147. (New) The solution formulation of either Claim 141 or Claim 142, wherein the preservative is m-cresol.

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148. (New) The solution formulation of Claim 147, wherein the FSH is an FSH variant, wherein the α-subunit has an amino acid sequence given in SEQ ID NO:5:

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS;

and wherein the ß-subunit has an amino acid sequence given in SEQ ID NO:11:

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELV
YETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGE.

149. (New) The solution formulation of either Claim 141 or Claim 142, wherein the concentration of FSH or FSH variant in the solution formulation is between about 50 μg/mL and about 200 μg/mL.

150. (New) The solution formulation of Claim 149, further comprising a buffer.

151. (New) The solution formulation of Claim 149, further comprising an isotonicity agent.

152. (New) A vial containing the solution formulation of either Claim 141 or 142.

153. (New) A cartridge containing the solution formulation of either Claim 141 or 142.

154. (New) An article of manufacture comprising a vial containing the solution formulation of either Claim 141 or 142.

155. (New) An article of manufacture comprising a cartridge containing the solution formulation of either Claim 141 or 142.

156. (New) An article of manufacture comprising a first vial comprising lyophilized FSH or an FSH variant and a second vial comprising a preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben, benzalkonium chloride, benzethonium chloride, sodium dehydroacetate, thimerosal, and mixtures thereof, in an aqueous diluent, wherein upon reconstitution of the lyophilized FSH or an FSH variant in the first vial with the contents of the second vial, the solution formulation of either Claim 141 or 142 is produced.